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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,344

Applicant(s)

MCDEVITT ET AL.

Examiner

Leon Y Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 309,347-395,428 and 440-496 is/are pending in the application.
- 4a) Of the above claim(s) 347-395,428 and 440-459 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 309 and 460-496 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040826
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. The election of Group I, claim 309, by Applicant in response to the Restriction Requirement has been noted. The Examiner also notes the addition of claims 460-496 in the revised claim listing. However, in Applicant's Arguments, it is stated in section "A. Claims in the Case" that "Claims 460-513 have been added." However, there is no evidence of claims 497-513 in the revised claim listing. Therefore, only claims 309 and 460-496 have been examined in the instant Office Action.

Information Disclosure Statement

2. The information disclosure statement filed 23 April 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of the non-patent literature listed in the document have not been provided with the instant application. In addition, the foreign patent document 439,182 has not been provided and cannot be located. The IDS has been placed in the application file, but the non-patent literature information and foreign patent document 439,182 referred to therein has not been considered.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Specifically, "Travis" is listed as the country of residence for inventors John T. McDevitt and Dean P. Neikirk. Since Travis is not an official country, the Declaration is defective.

Claim Objections

4. Claims 482-485 are objected to because of the following informalities: the instant claims recite the limitation wherein "the particle comprises a receptor molecule coupled to a polymeric resin" that has been previously recited in the parent claim (claim 309), and does not further limit the parent claim. Appropriate correction is required.

5. Claim 469 is objected to because of the following informalities: the instant claim recites the limitation wherein "wherein the cavity is configured to allow fluid to pass through the supporting member during use" that has been previously recited in claim 468, and is a repeated limitation. Appropriate correction is required.

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6. Claims 487-488 are objected to because of the following informalities: the instant claims recite the limitation of "a fluid delivery system coupled to the supporting member" that has been previously recited in claim 486, and is a repeated limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 309 and 460-496 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. In claim 309, line 5, the phrase "configured to", is vague and indefinite. The specification does not provide a definition on how the particle is configured, and it is not clear how the particle can "produce a signal" (line 6). Does the signal come from within the particle or is there a separate embodiment that is attached to the outside of the particle that produces the signal? Applicant is invited to clarify the limitation.

10. In claim 309, line 5; claim 461, line 2; and claims 468-469, line 1 of the claims, the phrase "the cavity" is vague and indefinite. The antecedent basis for this phrase is

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recited as “at least one cavity” (lines 3-4 of claim 309). In the event that there is a plurality of carriers, which one of the cavities is indicated in the instant phrase?

With regards to claim 309, it is not clear as to how one of ordinary skill in the art at the time of the invention would determine which cavity is referred to with regards to the limitation “the particle positioned with the cavity” (line 5).

With regards to claim 461, it is not clear as to how one of ordinary skill in the art at the time of the invention would determine which cavity is referred to with regards to the limitation “a plurality of particles positioned within the cavity” (lines 1-2).

With regards to claims 468-469, it is not clear as to how one of ordinary skill in the art at the time of the invention would determine which cavity is referred to with regards to the limitation “the cavity is configured to allow fluid to pass” (line 1 of the claims).

11. In claim 309, lines 6, 9, and 11; claim 467, line 3; claim 468, line 2; claim 469, line 2; and claim 471, line 5, the phrase “during use” is vague and indefinite. The specification does not provide a definition for the phrase and it is not clear what type of use the claim is referring to.

12. In claim 484, lines 4-5, the phrase “causes the first and second indicators to interact” is vague and indefinite. The specification does not provide a definition on how they interact, and it is not clear whether the indicators interact with each other, interact separately with the analyte, or perform another type of interaction.

13. Claim 495 is drawn to fluid that is "blood", which is an intended use of the parent claim (claim 309). Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

14. The term "substantially" in claims 460, 467, and 469 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

With regards to claim 460, it is not clear how the term limits the phrase "simultaneously detect a plurality of analytes" (line 3). Specifically, it is not clear whether simultaneous detection occurs since the instant term renders the phrase indefinite.

With regards to claim 467, it is not clear when an inhibition of "dislodgement of a particle" (lines 2-3) is obtained. Can there be a slight dislodgement, or no dislodgement? The phrase is unclear due to the instant term.

With regards to claim 469, it is not clear when a "bottom portion of the cavity"(lines 2-4) is obtained since it is not clear how less the width needs to be from the "top portion of the cavity" (line 3) and "width of the particle" (line 4). Applicant is invited to clarify the limitation.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 309, 460, 463-464, 467-469, 472, 474, 477-479, 481-482, 485, 491-493, and 495 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in light of Bogart et al (US 5,541,057).

In the instant claims, Lavigne et al reference teaches a system for detecting an analyte in a bodily fluid comprising: a light source; a sensor array, the sensor array comprising a supporting member comprising at least one cavity formed within the supporting member; a particle, the particle positioned within the cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte in the bodily fluid during use, and wherein the particle comprises a receptor molecule coupled to a polymeric resin; and a detector, the detector being configured to detect the

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signal produced by the interaction of the analyte with the particle during use; wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use, by disclosing an "electronic tongue" device wherein a light source (i) irradiates a series of beads held in pits (iii) through a cover plate (ii), wherein the transmitted light is analyzed with a CCD array (iv) (page 6430, Figure 1C and caption), wherein the beads are poly(ethylene glycol)-polystyrene (PEG-PS) resin beads that were derivatized with a variety of indicator molecules, wherein the indicators are selective for individual analytes (page 6429, left column, 3rd paragraph, lines 6-10).

With regards to claims 460 and 474, Lavigne et al reference teaches that the system comprises a plurality of particles positioned within a plurality of cavities, wherein the system is configured to substantially simultaneously detect a plurality of analytes in the fluid, and wherein the supporting member comprises a silicon wafer, by disclosing that a 3 x 3 array of beads was created, wherein resin beads are positioned within micromachined wells formed in Si/SiN wafers, thus confining the beads to individually addressable positions on a multicomponent chip, wherein a 3 x 3 array of beads was created to simultaneously identify a variety of analytes (page 6429, right column, 1st paragraph, lines 2-9; and Figure 1B).

With regards to claims 463-464 and 493, Lavigne et al reference teaches that the light source comprises a red light source, a green light source, and a blue light source, wherein the detector is configured to detect independently the absorbance of red light by the particle, and wherein the detector is configured to detect the absorbance of green

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light by the particle, wherein the detector is configured to detect the absorbance of blue light by the particle, and wherein the signal is a spectroscopic change, and wherein the detector is configured to measure the intensity of the spectroscopic change, by disclosing that data streams composed of red, green, and blue (RGB) light intensities were acquired for each of the individual beads, and that color attenuation was recorded for red, green, and blue with the CCD (page 6429, right column, 1st paragraph, lines 14-16; Figure 1C and caption; and Figure 2 and caption).

With regards to claims 467-469, Lavigne et al reference teaches a cover layer positioned at a fixed distance above the supporting member at a height to substantially inhibit dislodgement of a particle in a cavity during use, wherein the cavity is configured to allow fluid to pass through the supporting member during use, and wherein a width of a bottom portion of the cavity is substantially less than a width of a top portion of the cavity and wherein the width of the bottom portion of the cavity is substantially less than a width of the particle, by disclosing a cover plate (iv) (Figure 1C and caption), as stated above. The bead is indicated in Figure 1C as having a width larger than the distance between the cover plate and the top of the pit, thereby effectively preventing dislodgement of the bead from within the pit. Since the sensor device is used to detect analytes that are in solution, it is inherent that the placement of the cover plate over the multicomponent chip, which allows for space in between the said plate and top of said chip, provides a means for fluid movement through the chip, including the pits that hold the beads.

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With regards to claim 472, Lavigne et al reference teaches a sensing cavity formed on a bottom surface of the sensor array, by disclosing that the bottom of the pits is where light is transmitted to a CCD array (Figure 1 and caption).

With regards to claim 477, Lavigne et al reference teaches that an inner surface of the cavity is coated with a reflective material, by disclosing that micromachined wells are formed in Si/SiN wafers (page 6429, right column, 1st paragraph, lines 2-3), as stated above. Although Lavigne et al reference does not explicitly teach that the wells are reflective, silicon wafers are inherently reflective, as taught by Bogart et al reference in disclosing that silicon wafer is a polished reflective material (column 44, lines 43-44).

With regards to claims 478-479, Lavigne et al reference teaches that the detector comprises a charge-coupled device and comprises a semiconductor based photodetector, and wherein the detector is coupled to the sensor array, by disclosing a CCD array (iv) (page 6430, Figure 1C and caption), as stated above.

With regards to claims 481-482, Lavigne et al reference teaches that the detector comprises a fluorescence detector and wherein the particle comprises a receptor molecule coupled to a polymeric resin, by disclosing that responses were recorded with one specific and three nonspecific sensors, wherein the sensors are fluorescein (page 6429, right column, 2nd paragraph, lines 1-3), wherein signal transduction was accomplished by analysis of the absorption properties of the beads using a CCD (page 6429, right column, 1st paragraph, lines 9-11; and Figure 1C). Since detection is performed on beads using a CCD and the beads are tagged with sensors that are fluorescein, it is inherent that the CCD is required to be a fluorescence detector.

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Lavigne et al reference also teaches that resin beads were derivatized with indicator molecules that are selective for individual analytes (page 6429, left column, 3rd paragraph, lines 6-9), as stated above.

With regards to claim 485, Lavigne et al reference teaches that the particle further comprises an indicator, wherein the indicator is associated with the receptor such that in the presence of the analyte the indicator is displaced from the receptor to produce the signal, by disclosing that a resin bound boronic acid (1) was saturated with a fluorescently tagged sugar, resorufin- β -D-galactopyranoside (2), wherein the addition of D-fructose, which has a higher affinity than 2 for the boronic acid, results in a displacement of 2 and upon washing the released tag away from the resin, there is colorimetric modulation (page 6429, right column, 8th paragraph, lines 1-5).

With regards to claims 491-492, Lavigne et al reference teaches that the particle ranges from about 0.05 microns to about 500 microns and a volume of the particle changes when contacted with the fluid, by disclosing that the size of the wells was chosen so that they hold the beads in swollen and unswollen states, wherein swelling volumes of beads with a wet diameter of 250 μ m are on the order of 4 times the dry diameter of 210 μ m (page 6329, right column; 1st paragraph, lines 5-6; and 5th paragraph, lines 2-5).

Claim Rejections - 35 USC § 103

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17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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20. Claims 461, 466, 470-471, 473, 486-487, 490, and 494 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Pfoest et al (US 6,485,690 B1).

Lavigne et al reference has been disclosed above, but fails to teach channels in the supporting member, wherein the channels are configured to allow the fluid to flow through the channels into and away from the cavity, and wherein the cover layer is positioned such that a channel is formed between an upper surface of the supporting member and the cover layer such that fluid passes through the channel during use.

Pfoest et al reference teaches that the upper reservoir layer provides feed-through channels and center distribution layer comprises a plurality of channels that form a delivery system, in order to convey, transport, and process samples in a large multiplicity of sites without exposure to the atmosphere (column 2, lines 25-30 and 49-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al, with an upper reservoir layer that provides feed-through channels and a center distribution layer that comprises a plurality of channels that form a delivery system, as taught by Pfoest et al, in order to convey, transport, and process samples in a large multiplicity of sites without exposure to the atmosphere. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including the upper reservoir and center distribution layers as a cover layer in the device of Lavigne et al, since Lavigne et al teach a cover layer on a supporting member with a plurality of wells, and the upper and

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center layers taught by Pfof are designed to provide sample distribution to a plurality of sites in a supporting member.

With regards to claim 461, Pfof et al reference teaches that the system comprises a plurality of particles positioned within the cavity, by disclosing that one or more microbeads 31 may be positioned in the reaction well 30' for solid phase chemistry applications (column 7, lines 57-58 and Figures 10-18).

With regards to claim 466, Pfof et al reference teaches a cover layer, wherein the cover layer is removable, by disclosing a detachable bottom layer or plate that includes a plurality of submicrotiter reaction wells, in order to remove the bottom plate for incubation or analysis (column 2, lines 65-67 and column 3, lines 1-3).

With regards to claim 473, Pfof et al reference teaches that the supporting member comprises a plastic material, by disclosing that the plates 12, 14, and 16 can be made from any desirable material such as plastics, in order for the micro-sized reservoirs, channels, and reaction cells to be controllably etched or otherwise formed onto the plates using semiconductor fabrication techniques with a suitable chemical or laser etchant (column 6, lines 33-41; and Figure 9).

With regards to claims 486-487, Pfof et al reference teaches that a fluid delivery system is coupled to the supporting member, wherein the fluid delivery system is configured to introduce samples into the sensor array, and wherein the system is configured such that fluid passes through a reagent reservoir prior to passing over the sensor array, by disclosing that the processor 10 includes a top plate or layer, which is also called a reagent reservoir 12, in order to convey the materials (e.g. liquids) from the

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apertures 20 to positions above selected openings 22 and/or 24 in the middle layer (column 5, lines 57-58; column 6, lines 1-5; and Figure 9)

With regards to claim 494, Pfost et al reference teaches that the sensor array further comprises a vacuum chamber coupled to a conduit and the sensor array, and wherein the chamber is configured to provide a pulling force on the fluid in the sensor array, by disclosing that a pressure pumping mechanism, or a vacuum system is used, in order to assist in loading and distributing the reagents and other materials within the layers, to assist in draining and evacuation of excess reagents and wash solvents, and to fill or empty the microchannels and wells (column 6, lines 47-53 and column 8, lines 20-22)

21. Claim 462 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Stabile et al (US 5,854,684).

Lavigne et al reference has been disclosed above, but fails to teach that the light source comprises a light emitting diode.

Stabile et al reference teaches LEDs with relatively closely spaced light emitters, in order to have the advantages in cost and simplicity of housing requirements (column 11, lines 65-67 and column 12, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al, with LEDs with relatively closely spaced light emitters, as taught by Stabile et al, in order to have the advantages in cost and

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simplicity of housing requirements. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including an LED in the device of Lavigne et al, since Lavigne et al teach a light source, and an LED is one type of light source.

22. Claim 465 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Weersink et al (US 6,219,566 B1).

Lavigne et al reference has been disclosed above, but fails to teach that the light source comprises a white light source.

Weersink et al reference teaches that the light source 14 may be a white light lamp source, wherein the signal output is detected by a charge coupled device (CCD) detector, in order to excite a fluorophore in turbid medium (column 6, lines 22-39, especially lines 27-29, 32-33, and 37-38; and Figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al, with a white light lamp source, wherein the signal output is detected by a charge coupled device (CCD) detector, as taught by Weersink et al, in order to excite a fluorophore in turbid medium. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using a white light source, as taught by Weersink et al, in the device of Lavigne et al, since Lavigne et al teach a light source capable of producing light at a plurality of wavelengths, wherein the light is transmitted through a liquid and detected by a CCD,

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and the white light source taught by Weersink et al produces one type of wavelength that is also transmitted through a liquid medium and detectable by a CCD.

23. Claims 475-476 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Zanzucchi et al (US 5,681,484).

Lavigne et al reference has been disclosed above, but fails to teach that the supporting member comprises a plurality of layers of a dry film photoresist material.

Zanzucchi et al reference teaches a first and second photoresist layer in order to form channels in a substrate (column 3, lines 11-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al with a first and second photoresist layer, as taught by Zanzucchi et al, in order to form channels in a substrate. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including photoresist layers, as taught by Zanzucchi et al, in the device of Lavigne et al, since Lavigne et al teach micromachined wells in a substrate for microscale assays, and the photoresist layers taught by Zanzucchi et al are used to etch channels in substrates for a microfluidic assay.

24. Claim 480 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Walt et al (US 6,023,540).

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Lavigne et al reference has been disclosed above, but fails to teach that the detector comprises an ultraviolet detector.

Walt et al reference teaches fiber optic strands using ultraviolet wavelengths in combination with the absorption coefficient in order to determine the concentration of specific analytes of interest by spectral measurement (column 2, lines 22-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al with fiber optic strands using ultraviolet wavelengths in combination with the absorption coefficient, as taught by Walt et al, in order to determine the concentration of specific analytes of interest by spectral measurement. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including a fiber optic strand using ultraviolet wavelengths, as taught by Walt et al, in the device of Lavigne et al, since Lavigne et al teach a detection system that can detect a multitude of wavelengths.

25. Claim 483 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Barany et al (US 5,235,028).

Lavigne et al reference has been disclosed above and additionally teaches poly(ethylene glycol)-polystyrene (PEG-PS) resin beads (page 6429, left column, 3rd paragraph, lines 6-7), but fails to teach that the polymeric resin comprises polystyrene-polyethylene glycol-divinyl benzene.

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Barany et al reference teaches that a particularly preferred support is an amino-functionalized polystyrene-co-1% divinylbenzene, wherein most of the amino groups become substituted with polyethylene glycol derivatives (column 5, lines 27-35), in order to produce PEG-PS supports that have the desirable characteristic of being able to swell in a variety of solvents (column 6, lines 48-51).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al with an amino-functionalized polystyrene-co-1% divinylbenzene, wherein most of the amino groups become substituted with polyethylene glycol derivatives, as taught by Barany et al, in order to produce PEG-PS supports that have the desirable characteristic of being able to swell in a variety of solvents. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including a PEG-PS-divinyl benzene resin, as taught by Barany et al, in the device of Lavigne et al, since Lavigne et al teach PEG-PS resin beads, and PEG-PS beads derivatized with divinyl benzene is one type of PEG-PS support.

26. Claims 484 and 496 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Chandler et al (US 6,268,222 B1).

Lavigne et al reference has been disclosed above, but fails to teach that the particle further comprises a first indicator and a second indicator, the first and second indicators being coupled to the receptor, wherein an interaction of the receptor with the

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analyte causes the first and second indicators to interact such that the signal is produced; wherein the particle comprises a biopolymer coupled to the polymeric resin, and wherein the biopolymer undergoes a chemical reaction in the presence of the analyte to produce a signal.

Chandler et al reference teaches a fluorescent polymeric article, comprising a carrier microparticle carrying one or more nanoparticles with multiple fluorescent signals, wherein each such population of microparticles, characterized by at least two fluorescent signals, is combined with an analytical reactant capable of binding a specific analyte of interest in a clinical or test sample (column 12, lines 6-9 and 36-39), wherein the dyes have the same or overlapping excitation spectra, but possess distinguishable emission spectra (column 9, lines 41-44), wherein beads are formed from natural macromolecules (column 6, lines 57-60) and nanoparticles are preferably made of the same material as microparticles (column 7, lines 12-13), and wherein the polymeric article can produce hybridization in nucleic acid assays with a product of the label (column 16, lines 13-19), in order to detect various analytes of interest in various types of analyte assays such as immunoassays, nucleic acid assays, affinity purification, and other medical, diagnostic, and industrial applications (column 12, lines 58-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al with a fluorescent polymeric article, comprising a carrier microparticle carrying one or more nanoparticles with multiple fluorescent signals, wherein each such population of microparticles, characterized by at least two fluorescent signals, is combined with an analytical reactant capable of binding

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a specific analyte of interest in a clinical or test sample, wherein the dyes have the same or overlapping excitation spectra, but possess distinguishable emission spectra, wherein beads are formed from natural macromolecules and nanoparticles are preferably made of the same material as microparticles, and wherein the polymeric article can produce hybridization in nucleic acid assays with a product of the label, as taught by Chandler et al, in order to detect various analytes of interest in various types of analyte assays such as immunoassays, nucleic acid assays, affinity purification, and other medical, diagnostic, and industrial applications. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including the fluorescent polymeric articles, as taught by Chandler et al, in the device of Lavigne et al, since Lavigne et al teach the application of tagged beads in assays to determine the presence of an analyte, and the multiple-tagged polymeric articles are capable of performing diagnostic assays to determine a plurality of analyte types.

27. Claims 488-489 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Pfoest et al (US 6,485,690 B1), as applied to claims 486-487 above, and further in view of Fernwood et al (US 4,493,815).

Lavigne et al and Pfoest et al references have been disclosed, but fail to teach a filter coupled to the fluid delivery system, wherein the system is configured such that the fluid passes through a filter prior to passing over the sensor array.

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Fernwood et al reference teaches a microporous membrane 3 that is placed immediately below the upper template, in order to immobilize a biochemical species, including antigens, antibodies, conjugates, blocking agents, cells, precipitates, and others (column 3, lines 49-53 and Figure 1), wherein the immobilization effectively filters particulates and allows non-immobilized components to travel down to the lower template 5 (column 3, lines 1-2 and Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al and Pfoest et al, with a microporous membrane 3 that is placed immediately below the upper template, as taught by Fernwood et al, in order to immobilize a biochemical species, including antigens, antibodies, conjugates, blocking agents, cells, precipitates, and others, wherein the immobilization effectively filters particulates and allows non-immobilized components to travel down to the lower template 5. One of ordinary skill in the art would have reasonable expectation of success in including a membrane, as taught by Fernwood et al, in the device of Lavigne et al and Pfoest et al, since Lavigne et al and Pfoest et al teach a device with a plurality of wells in an array fashion and includes embodiments that would facilitate appropriate placement of the membrane in the device, which is designed to be placed in a device that accommodates an array of cavities. Since the membrane is capable of being placed under the upper template, as taught by Fernwood et al, it would be placed under the upper layer of Lavigne et al and Pfoest et al device, and in direct contact with the fluid delivery system of Pfoest et al reference.

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28. Claim 495 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430) in view of Kroy et al (US 5,252,294).

Lavigne et al reference has been disclosed above, but fails to teach that the fluid is a bodily fluid and that the fluid is blood.

Kroy et al reference teaches that substances to be examined in cavities 2 of block 1 can be substances in blood, in order to determine the pH values of blood sugar, or blood cholesterol, or for detecting narcotics in blood (column 3, lines 58-62; column 4, lines 31-41; and Figure 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Lavigne et al, with substances to be examined in cavities 2 of block 1 that can be substances in blood, as taught by Kroy et al, in order to determine the pH values of blood sugar, or blood cholesterol, or for detecting narcotics in blood. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in examining blood in the device of Lavigne et al, since Lavigne et al teach the analysis of fluids in a device with microwells, and blood is one type of fluid that can be analyzed in a device with cavities.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 309 and 460-496 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 10-19, 23-24, 28-29, and 174 of copending Application No. 09/287,248 in view of Lavigne et al (J. Am. Chem. Soc. 1998, 120: 6429-6430).

Both the instant and copending applications claim a system comprising: a light source, a sensor array comprising more than one cavity formed within a supporting member, a particle positioned within a cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte during use, and a detector that detects the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

However, the instant application includes a narrower limitation in the independent claim of the particle comprising a receptor molecule coupled to a polymeric resin.

Although the copending application does not include the narrower limitation of a particle comprising a receptor molecule coupled to a polymeric resin in the independent claim, the said limitation is recited in claim 23 and is therefore part of the claimed

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invention. In addition, the copending application recites a "plurality of cavities" (line 4), a "plurality of particles" (line 7), "a cover layer" (line 9) and "wherein the light source provides an area of light on an upper surface of the sensor array during use, wherein the area of light encompasses two or more cavities" (lines 17-19), which are narrower limitations than in the claims of the instant application.

Therefore, the claims of the copending application anticipate the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

31. Claims 309 and 460-496 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 413-446, 450-451, 461-465, 490-492, 726, and 730 of copending Application No. 09/616,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant and copending applications claim a system comprising: a light source, a sensor array comprising at least one cavity formed within a supporting member, a particle positioned within a cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte during use, and a detector that is configured to detect the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

However, the instant application includes a narrower limitation in the independent claim of the particle comprising a receptor molecule coupled to a polymeric resin. The copending application also includes a narrower limitation in the independent claim of a vacuum apparatus.

Although the copending application does not include the narrower limitation of a particle comprising a receptor molecule coupled to a polymeric resin in the independent claim, the said limitation is recited in claim 445 and is therefore part of the claimed invention. In addition, although the instant application does not include a vacuum apparatus in the independent claim, a vacuum chamber is recited in claim 494 and is therefore included in the claimed invention. Therefore, the claims of the instant application anticipate the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

32. Claims 309 and 460-496 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 21-34, 37-69, 74, 76-114, 116-119, 121-147, 327-360, and 363-377 of copending Application No. 09/775,342. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant and copending applications claim a system comprising: a light source, a sensor array comprising at least one cavity formed within a supporting member, a particle positioned within a cavity, wherein the particle is configured to

produce a signal when the particle interacts with the analyte during use, and a detector that is configured to detect the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

However, the instant application includes the narrower limitations in the independent claim of the particle comprising a receptor molecule coupled to a polymeric resin.

Although the copending application does not include the narrower limitation of a particle comprising a receptor molecule coupled to a polymeric resin in the independent claim, the said limitation is recited in claim 21 and is therefore part of the claimed invention. Therefore, the claims of the instant application anticipate the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

33. Claims 309 and 460-496 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-21, and 29-37 of copending Application No. 10/427,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant and copending applications claim a system comprising: a light source, a sensor array comprising a cavity formed within a supporting member, a

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particle positioned within a cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte during use, and a detector that is configured to detect the signal.

However, the instant application includes the narrower limitations in the independent claim of the particle comprising a receptor molecule coupled to a polymeric resin and wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

Although the copending application does not include the narrower limitation of a particle comprising a receptor molecule coupled to a polymeric resin in the independent claim, the said limitation is recited in claim 13 and is therefore part of the claimed invention. In addition, since the claimed invention of the copending application includes a light emitting diode (claims 2-4), it would have been obvious to one of ordinary skill in the art at the time of the invention to use the diode as a light source and in doing so, it is necessarily required to apply the light onto the particle and position the detector such that the light passes from the light source, through the particle, and onto the detector, in order to detect the signal produced by the particles during use. In addition, the copending application recites a "plurality of cavities" (lines 4-5), and a "plurality of particles" (line 6), which are narrower limitations than in the claims of the instant application. Therefore, the claims of the instant application anticipate the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 309 and 460-496 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 10-18, and 23-31 of U.S. Patent No. 6,602,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant application and US Patent claim a system comprising: a light source, a sensor array comprising at least one cavity formed within a supporting member, a particle positioned within a cavity, and a detector that is configured to detect the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

The US Patent includes the narrower limitations in the independent claim wherein the particle comprises a biopolymer coupled to a polymeric resin, wherein the biopolymer undergoes a chemical reaction in the presence of the analyte to produce a signal, and a cover positioned over the cavity, wherein the cover is positioned at a fixed distance over the cavity such that a channel is formed between the supporting member and the cover to allow the fluid to enter the cavity via the formed channel, and wherein the fixed distance is such that the cover inhibits dislodgement of the particle from the cavity during use.

However, the instant application recites the said limitations in claims 496 and 471, respectively, and the limitations are therefore part of the claimed invention. Therefore, the claims of the US Patent anticipate the claims of the instant application.

35. Claims 309 and 460-496 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-21, 25-26, and 36-37 of U.S. Patent No. 6,680,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant application and US Patent claim a system comprising: a light source, a sensor array comprising at least one cavity formed within a supporting member, a particle positioned within a cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte during use, and a detector that is configured to detect the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

The US Patent includes the narrower limitations wherein the cavity is configured such that the fluid entering the cavity passes through the supporting member, and a cover, wherein the cover inhibits dislodgement of the particle from the cavity during use, in the independent claim. However, the said limitations are recited in claims 469 and 471, respectively, in the instant application and are therefore part of the claimed invention.

In addition, the US Patent recites the limitation "a cover positioned at a distance above the upper surface of the supporting member such that an opening is formed between the supporting member and the cover to allow the fluid to enter the cavity via

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the opening", which is narrower than the claims in the instant application and covers the claims of the instant application.

Therefore, the claims of the US Patent anticipate the claims of the instant application.

36. Claims 309 and 460-496 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-23, 27-29, and 31 of U.S. Patent No. 6,713,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant application and US Patent claim a system comprising: a light source, a sensor array comprising at least one cavity formed within a supporting member, a particle positioned within a cavity, wherein the particle is configured to produce a signal when the particle interacts with the analyte during use, and a detector that is configured to detect the signal produced by the interaction of the analyte with the particle during use, wherein the light source and detector are positioned such that light passes from the light source, to the particle, and onto the detector during use.

The US Patent also includes the limitations of a spacer layer, a sensor layer, and a cover layer in lines 4-19, which are narrower than the claims in the instant application and would therefore cover the claims of the instant application.

Therefore, the claims of the US Patent anticipate the claims of the instant application.

Conclusion

37. No claims are allowed.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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